

REMARKS

Claims 21-26 are pending in the present application. In the Office Action mailed October 26, 2005, the Examiner rejected these claims under 35 U.S.C. §102 and 103. Applicant notes with appreciation that prior rejections were removed.

The Examiner has raised the following rejections:

- I. Claims 21-22 are rejected under 35 U.S.C. §102 (b), as allegedly being anticipated by Moreckie *et al.*, Cancer Immunol. Immunother. 41(4):236-242, Oct. 1995 (hereinafter "Moreckie"); and
- II. Claims 21-26 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Moreckie in view of Kaminski, *et al.*, J. Immunol. 138(4):1289-1296 (1987) (hereinafter "Kaminski") and Gupta, *et al.*, Vaccines 13(14):1263-1276 (1995) (hereinafter "Gupta").

Applicant respectfully requests reconsideration of the application in view of the amendments and comments provided herein. The rejections will be addressed in the order listed above.

I. Claims 21-22 stand rejected as allegedly being anticipated by Moreckie. Moreckie describes the used of irradiated intact B-cell tumor cells for inducing an immune response (page 236, title and abstract). The Examiner asserts that the term "recombinant" provides no patentable distinction for the recited multivalent composition over the whole-cell compositions of Moreckie in that "recombinant" is asserted to be only the process by which the product is made, not a structural difference in the product. Applicant respectfully disagrees.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. MPEP 2131, citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d. 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Moreckie does not teach or describe, either expressly or inherently, all of the elements of the claims.

The present claims are not to compositions, but rather *are to methods*. As such, the steps of the method are elements that must be considered for determining patentability. Claim 21

recites the step of providing a recombinant composition (*i.e.*, providing a multivalent composition comprising at least two recombinant heavy chain variable regions of immunoglobulin molecules derived from said subject's B-cell lymphoma cells). Moreckie does not teach or suggest providing a recombinant composition comprising heavy chain variable regions that differ by at least one idiotope. Thus, Moreckie cannot anticipate the claims¹.

Nonetheless, for business reasons and without acquiescing to the Examiner's arguments, Applicant herein amends the claims to recite distinct steps of providing a multivalent composition comprising at least two recombinant heavy chain variable regions. Support for the recited steps is found throughout the specification, *e.g.*, at page 10 line 27 to page 11 line 16, and these steps are not new matter. Moreckie does not teach or suggest the process of isolating nucleic acids from a subject's malignant cells, inserting the nucleic acids comprising nucleotide sequences encoding heavy chain variable regions into an expression vector, transforming a parent cell line with that expression vector, identifying a transformed cell expressing at least two recombinant heavy chain variable regions, and purifying recombinant heavy chain variable regions from the transformed cell. As such, the claims as amended are not anticipated by Moreckie. Applicant thus respectfully requests that these rejections be removed.

II. Claims 21-26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Moreckie in view of Kaminski and Gupta. Prima facie obviousness requires that the prior art teach or suggest all the claim limitations (MPEP § 2143). Applicant submits that the references cited by the Examiner fail to teach the elements of the present claims.

As discussed in detail above, Moreckie does not teach or suggest the providing of the recombinant multivalent composition of the claims, much less the process of isolating nucleic acids from a subject's malignant cells, inserting the nucleic acids comprising nucleotide sequences encoding heavy chain variable regions into an expression vector, transforming a parent cell line with that expression vector, identifying a transformed cell expressing at least two recombinant heavy chain variable regions, and purifying recombinant heavy chain variable regions from the transformed cell. Kaminski and Gupta do not cure this deficiency. Kaminski teaches the isolation of Id protein from murine lymphoma cells by rescue fusion (page 1289, 2nd column), and the use of certain carrier proteins and adjuvants. Kaminski provides the isolation

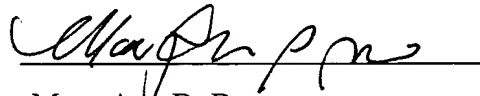
¹ Applicant does not acquiesce that Moreckie teaches any or all of the other elements of the unamended claims.

of a single Id protein, 38C13, and this composition is not multivalent in accordance with the present invention. Further, Kaminski does not teach isolation of Id proteins using recombinant expression as recited in the claims. Gupta teach a variety of adjuvants. Neither Kaminski nor Gupta teach a method of administering recombinant multivalent compositions of the present claims. For these reasons, Applicant respectfully asserts that these references, whether taken alone or in combination, do not provide the elements of the present claims. Thus, the claims are not obvious and Applicant respectfully requests that these rejections be removed.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that all grounds for rejection have been addressed and should be removed, and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

Dated: April 12, 2006



Mary Ann D. Brow
Registration No. 42,363
MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105